

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

IN RE: ETHICON PHYSIOMESH)
FLEXIBLE COMPOSITE) MDL DOCKET NO. 2782
HERNIA MESH PRODUCTS)
LIABILITY LITIGATION)
)
) CIVIL ACTION NO.
This Document Relates to) 1:17-MD-02782-RWS
ALL CASES)
)

MASTER ANSWER AND JURY DEMAND
OF DEFENDANT ETHICON, INC.
TO MASTER LONG FORM COMPLAINT

Defendant Ethicon, Inc. (“Ethicon”) responds to plaintiffs’ Master Long Form Complaint (“Complaint”) as follows:

The unnumbered introductory paragraph of plaintiffs’ Complaint makes no allegation against Ethicon and requires no response by Ethicon.

I. RESPONSE TO “PARTIES”

RESPONSE TO “PLAINTIFFS”

1. Ethicon lacks sufficient knowledge or information to know whether any particular plaintiff used any of its products, and therefore Ethicon denies that allegation. Ethicon admits that it designed, manufactured, distributed, and sold

PHYSIOMESH™ Flexible Composite Mesh (“Physiomes”) for uses consistent with the packaging and labeling. Ethicon admits further that it designed, distributed and sold SECURESTRAP® Absorbable Strap Fixation Device (“SecureStrap”) for uses consistent with the packaging and labeling, but denies that it manufactured that device. Johnson & Johnson does not design, manufacture, distribute or sell any product. Ethicon denies all remaining allegations contained in Paragraph 1 of plaintiffs’ Complaint and all allegations inconsistent with the foregoing. Ethicon specifically denies that the term “Physiomes” “includes the product with and without the SecureStrap fixation device.” SecureStrap and Physiomes are separate and distinct products, and this Multi-District Litigation concerns Physiomes, not SecureStrap.

2. The allegations contained in Paragraph 2 of plaintiffs’ Complaint do not require a response from Ethicon. If Ethicon is mistaken in that regard, then Ethicon lacks sufficient knowledge or information to know whether any particular plaintiff used any of its products, and therefore Ethicon denies that allegation. Ethicon also lacks sufficient knowledge or information so as to form a belief as to the truth of the remaining allegations contained in Paragraph 2 of plaintiffs’ Complaint and, therefore, denies those allegations.

RESPONSE TO “DEFENDANTS”

3. Ethicon admits that Johnson & Johnson is a business corporation organized under the laws of the State of New Jersey with its principal place of business at One Johnson & Johnson Plaza in New Brunswick, New Jersey. Any information contained on Johnson & Johnson’s website speaks for itself. Ethicon denies all allegations contained in Paragraph 3 of plaintiffs’ Complaint that are inconsistent with the foregoing.

4. With respect to the allegations contained in Paragraph 4 of the Complaint, Johnson & Johnson is a holding company for companies with a primary focus of providing products and services related to human health and well-being. Each of these subsidiary companies operates independently of Johnson & Johnson. Johnson & Johnson’s subsidiaries are organized in three business segments: Consumer, Pharmaceutical and Medical Devices. The companies within these segments are financially and operationally independent. Ethicon admits that it designed, developed, manufactured, tested, marketed, promoted, distributed, and sold Physiomesh for uses consistent with the packaging and labeling. Ethicon further admits that it designed, developed, marketed, promoted, distributed, and sold SecureStrap for uses consistent with the packaging and labeling. Ethicon denies that it manufactured SecureStrap. Ethicon further admits that Mr. Gary

Pruden in 2009 became Company Group Chairman, Ethicon. In 2012, he was named Worldwide Chairman, Global Surgery Group, and in 2015, Worldwide Chairman, Medical Devices. Mr. Pruden retired effective June 1, 2017. Ethicon denies the remaining allegations contained in Paragraph 4 of plaintiffs' Complaint and all allegations inconsistent with the foregoing.

5. Ethicon admits only that it is a business corporation organized under the laws of the State of New Jersey with its principal place of business in Somerville, New Jersey, and that it is a wholly owned subsidiary of Johnson & Johnson. Ethicon denies the remaining allegations contained in Paragraph 5 of plaintiffs' Complaint and all allegations inconsistent with the foregoing.

6. Ethicon admits that it researched, developed, tested, manufactured, produced, marketed, promoted, and/or sold Physiomesh for uses consistent with the packaging and labeling. Ethicon further admits that it has researched, developed, tested, marketed, promoted, and sold SecureStrap for uses consistent with the packaging and labeling. Ethicon denies that it manufactured SecureStrap. Physiomesh and SecureStrap are distinct products, and were sold separately. Ethicon denies the remaining allegations contained in Paragraph 6 of plaintiffs' Complaint and all allegations inconsistent with the foregoing.

7. Ethicon admits only that it researched, developed, designed, manufactured, produced, tested, marketed, promoted, distributed, and/or sold Physiomesh for uses consistent with the packaging and labeling. Ethicon lacks sufficient knowledge or information to know whether any particular plaintiff used any of its products, and therefore Ethicon denies that allegation. Ethicon denies the remaining allegations contained in Paragraph 7 of plaintiffs' Complaint and all allegations inconsistent with the foregoing.

8. Ethicon denies the allegations contained in Paragraph 8 of plaintiffs' Complaint.

9. Ethicon denies the allegations contained in Paragraph 9 of plaintiffs' Complaint.

10. The first sentence of Paragraph 10 of plaintiffs' Complaint states a legal conclusion as opposed to a factual allegation and requires no response by Ethicon. Ethicon denies that plaintiffs' Complaint accurately or completely states the nature of any duties allegedly owed by Defendants and Ethicon further denies that Defendants breached any duty with respect to the plaintiffs. Physiomesh is safe and effective for uses consistent with the packaging and labeling. Ethicon denies the remaining allegations contained in Paragraph 10 of plaintiffs' Complaint and all allegations inconsistent with the foregoing.

II. RESPONSE TO “JURISDICTION AND VENUE”

11. Ethicon lacks sufficient knowledge or information so as to form a belief as to the truth of the allegations contained in Paragraph 11 of plaintiffs’ Complaint, and, therefore, denies those allegations.

12. Paragraph 12 of plaintiffs’ Complaint states a legal conclusion as opposed to a factual allegation and requires no response by Ethicon. To the extent a response is required, Ethicon denies the allegations contained in Paragraph 12 of plaintiffs’ Complaint.

13. Ethicon lacks sufficient knowledge or information so as to form a belief as to the truth of the allegations contained in the first sentence of Paragraph 13 of plaintiffs’ Complaint, and, therefore, denies those allegations. The second sentence of Paragraph 13 of plaintiffs’ Complaint states a legal conclusion as opposed to a factual allegation and requires no response by Ethicon. To the extent a response is required, Ethicon denies the allegations contained in Paragraph 13 of plaintiffs’ Complaint.

III. RESPONSE TO “FACTS COMMON TO ALL COUNTS”

14. Ethicon admits only that it manufactured, sold, and/or distributed Physiomesh for uses consistent with the packaging and labeling. Ethicon denies the

remaining allegations contained in Paragraph 14 of plaintiffs' Complaint and all allegations inconsistent with the foregoing.

15. Ethicon admits only that it researched, designed, developed, tested, manufactured, produced, marketed, promoted, distributed, and sold Physiomesh for uses consistent with the packaging and labeling. Ethicon denies the remaining allegations contained in Paragraph 15 of plaintiffs' Complaint and all allegations inconsistent with the foregoing.

16. Ethicon lacks sufficient knowledge or information to know whether any particular plaintiff used any of its products, or the circumstances under which any particular plaintiff may have used any of its products, and therefore Ethicon denies those allegations. Ethicon admits only that it designed, manufactured, and sold Physiomesh for uses consistent with the packaging and labeling. Ethicon denies the remaining allegations contained in Paragraph 16 of plaintiffs' Complaint and all allegations inconsistent with the foregoing.

17. Ethicon admits only that Physiomesh is safe and effective for uses consistent with the packing and labeling. Ethicon denies the remaining allegations contained in Paragraph 17 of plaintiffs' Complaint and all allegations inconsistent with the foregoing.

18. Ethicon denies the allegations contained in Paragraph 18 of plaintiffs' Complaint.

19. Ethicon admits only that Physiomesh has five layers, including two layers of Monocryl film and a layer of polydioxanone film and that Ethicon promoted Physiomesh for uses consistent with the packaging and labeling. Ethicon denies the remaining allegations contained in Paragraph 19 of plaintiffs' Complaint and all allegations inconsistent with the foregoing.

20. Ethicon denies the allegations contained in Paragraph 20 of plaintiffs' Complaint.

21. Ethicon denies the allegations contained in Paragraph 21 of plaintiffs' Complaint.

22. Ethicon denies the allegations contained in Paragraph 22 of plaintiffs' Complaint.

23. Ethicon denies the allegations contained in Paragraph 23 of plaintiffs' Complaint.

24. Ethicon denies the allegations contained in Paragraph 24 of plaintiffs' Complaint.

25. Ethicon denies the allegations contained in Paragraph 25 of plaintiffs' Complaint.

26. Ethicon denies the allegations contained in Paragraph 26 of plaintiffs' Complaint.

27. Ethicon denies the allegations contained in Paragraph 27 of plaintiffs' Complaint.

28. Ethicon denies the allegations contained in Paragraph 28 of plaintiffs' Complaint.

29. Ethicon admits only that it designed and sold Physiomesh for uses consistent with the packaging and labeling. Ethicon denies the remaining allegations contained in Paragraph 29 of plaintiffs' Complaint and all allegations inconsistent with the foregoing.

30. Ethicon lacks sufficient knowledge or information to know whether any particular plaintiff used any of its products, and therefore Ethicon denies that allegation. Ethicon admits only that in May 2016 a notice was issued regarding Physiomesh, the content of which speaks for itself. Ethicon denies the remaining allegations contained in Paragraph 30 of plaintiffs' Complaint and denies all allegations inconsistent with the foregoing.

31. Ethicon denies the allegations contained in Paragraph 31 of plaintiffs' Complaint.

32. Ethicon denies the allegations contained in Paragraph 32 of plaintiffs' Complaint.

33. Ethicon denies the allegations contained in Paragraph 33 of plaintiffs' Complaint.

34. Ethicon denies the allegations contained in Paragraph 34 of plaintiffs' Complaint.

IV. RESPONSE TO "CAUSES OF ACTION"

RESPONSE TO "COUNT I Strict Product Liability: Defective Design"

35. Ethicon incorporates by reference its responses to each and every allegation contained in plaintiffs' Complaint as if fully copied and set forth at length herein.

36. Ethicon denies the allegations contained in Paragraph 36 of plaintiffs' Complaint.

37. Ethicon denies the allegations contained in Paragraph 37 of plaintiffs' Complaint.

38. Ethicon admits only that it sold Physiomesh for uses consistent with the packaging and labeling. Ethicon lacks sufficient knowledge or information to know whether any particular plaintiff used any of its products, and therefore

Ethicon denies that allegation. Ethicon denies the remaining allegations contained in Paragraph 38 of plaintiffs' Complaint and any allegation inconsistent with the foregoing.

39. Ethicon lacks sufficient knowledge or information to know whether any particular plaintiff used any of its products and/or whether the alleged implantation of Physiomesh in any particular plaintiff's body was medically reasonable, and therefore Ethicon denies those allegations. Ethicon admits only that it designed, manufactured, and sold Physiomesh for uses consistent with the packaging and labeling. Ethicon denies the remaining allegations contained in Paragraph 39 of plaintiffs' Complaint.

40. Ethicon denies the allegations contained in Paragraph 40 of plaintiffs' Complaint.

41. Ethicon admits only that it marketed and promoted Physiomesh for uses consistent with the packaging and labeling and that the device is composed of both nonabsorbable and absorbable components. Ethicon denies the remaining allegations contained in Paragraph 41 of plaintiffs' Complaint and all allegations inconsistent with the foregoing.

42. Ethicon denies the allegations contained in Paragraph 42 of plaintiffs' Complaint.

43. Ethicon denies the allegations contained in Paragraph 43 of plaintiffs' Complaint.

44. Ethicon denies the allegations contained in Paragraph 44 of plaintiffs' Complaint.

45. Ethicon admits only that it designed Physiomesh for uses consistent with the packaging and labeling. Ethicon denies the remaining allegations contained in Paragraph 45 of plaintiffs' Complaint and all allegations inconsistent with the foregoing.

46. Ethicon denies the allegations contained in Paragraph 46 of plaintiffs' Complaint.

47. Ethicon denies the allegations contained in Paragraph 47 of plaintiffs' Complaint.

48. Ethicon denies the allegations contained in Paragraph 48 of plaintiffs' Complaint.

49. Ethicon denies the allegations contained in Paragraph 49 of plaintiffs' Complaint.

50. Ethicon denies the allegations contained in Paragraph 50 of plaintiffs' Complaint.

**RESPONSE TO “COUNT II
Strict Product Liability: Failure to Warn”**

51. Ethicon incorporates by reference its responses to each and every allegation contained in plaintiffs’ Complaint as if fully copied and set forth at length herein.

52. Ethicon denies the allegations contained in Paragraph 52 of plaintiffs’ Complaint.

53. Ethicon denies the allegations contained in Paragraph 53 of plaintiffs’ Complaint.

54. Ethicon denies the allegations contained in Paragraph 54 of plaintiffs’ Complaint.

55. Ethicon admits only that it sold Physiomesh for uses consistent with the packaging and labeling. Ethicon lacks sufficient knowledge or information to know whether any particular plaintiff used any of its products, and therefore Ethicon denies that allegation. Ethicon denies the remaining allegations contained in Paragraph 55 of plaintiffs’ Complaint and any allegation inconsistent with the foregoing.

56. Ethicon denies the allegations contained in Paragraph 56 of plaintiffs’ Complaint.

57. Ethicon denies the allegations contained in Paragraph 57 of plaintiffs' Complaint.

58. Ethicon denies the allegations contained in Paragraph 58 of plaintiffs' Complaint.

59. Ethicon denies the allegations contained in Paragraph 59 of plaintiffs' Complaint.

60. Ethicon denies the allegations contained in Paragraph 60 of plaintiffs' Complaint.

61. Ethicon denies the allegations contained in Paragraph 61 of plaintiffs' Complaint.

62. Ethicon admits only that it marketed and promoted Physiomesh for uses consistent with the packaging and labeling. Ethicon lacks sufficient knowledge or information to know whether any particular plaintiff used any of its products, and therefore Ethicon denies that allegation. Ethicon denies the remaining allegations contained in Paragraph 62 of plaintiffs' Complaint and all allegations inconsistent with the foregoing.

63. Ethicon denies the allegations contained in Paragraph 63 of plaintiffs' Complaint.

64. Ethicon denies the allegations contained in Paragraph 64 of plaintiffs' Complaint.

65. Ethicon denies the allegations contained in Paragraph 65 of plaintiffs' Complaint.

66. Ethicon denies the allegations contained in Paragraph 66 of plaintiffs' Complaint.

67. Ethicon denies the allegations contained in Paragraph 67 of plaintiffs' Complaint.

**RESPONSE TO "COUNT III
Strict Product Liability: Manufacturing Defect"**

68. Ethicon incorporates by reference its responses to each and every allegation contained in plaintiffs' Complaint as if fully copied and set forth at length herein.

69. Ethicon denies the allegations contained in Paragraph 69 of plaintiffs' Complaint.

70. Ethicon denies the allegations contained in Paragraph 70 of plaintiffs' Complaint.

71. Ethicon denies the allegations contained in Paragraph 71 of plaintiffs' Complaint.

72. Ethicon denies the allegations contained in Paragraph 72 of plaintiffs' Complaint.

73. Ethicon denies the allegations contained in Paragraph 73 of plaintiffs' Complaint.

74. Ethicon denies the allegations contained in Paragraph 74 of plaintiffs' Complaint.

75. Ethicon denies the allegations contained in Paragraph 75 of plaintiffs' Complaint.

**RESPONSE TO "COUNT IV
Negligence"**

76. Ethicon incorporates by reference its responses to each and every allegation contained in plaintiffs' Complaint as if fully copied and set forth at length herein.

77. Paragraph 77 of plaintiffs' Complaint states a legal conclusion as opposed to a factual allegation and requires no response by Ethicon. Ethicon denies that plaintiffs' Complaint accurately or completely sets forth any alleged duties owed by Defendants, and Ethicon further denies that Defendants breached any duty with respect to the plaintiffs. Ethicon admits that it designed, tested, manufactured, marketed, and distributed Physiomesh for uses consistent with the

packaging and labeling. Ethicon denies the remaining allegations contained in Paragraph 77 of plaintiffs' Complaint and all allegations inconsistent with the foregoing.

78. Ethicon denies the allegations contained in Paragraph 78 of plaintiffs' Complaint.

79. Ethicon denies the allegations contained in Paragraph 79 of plaintiffs' Complaint.

80. Ethicon denies the allegations contained in Paragraph 80 of plaintiffs' Complaint, including subparts (a.) – (g.).

81. Ethicon denies the allegations contained in Paragraph 81 of plaintiffs' Complaint, including subparts (a.) – (h.).

82. Ethicon denies the allegations contained in Paragraph 82 of plaintiffs' Complaint, including subparts (a.) – (t.).

83. Ethicon denies the allegations contained in Paragraph 83 of plaintiffs' Complaint.

84. Ethicon denies the allegations contained in Paragraph 84 of plaintiffs' Complaint.

85. Ethicon denies the allegations contained in Paragraph 85 of plaintiffs' Complaint.

86. Ethicon denies the allegations contained in Paragraph 86 of plaintiffs' Complaint.

**RESPONSE TO "COUNT V
Consumer Protection Laws"**

87. Ethicon incorporates by reference its responses to each and every allegation contained in plaintiffs' Complaint as if fully copied and set forth at length herein.

88. Ethicon lacks sufficient knowledge or information to know whether any particular plaintiff used any of its products, and therefore Ethicon denies that allegation. Ethicon denies the remaining allegations contained in Paragraph 88 of plaintiffs' Complaint.

89. Ethicon denies the allegations contained in Paragraph 89 of plaintiffs' Complaint.

90. Ethicon denies the allegations contained in Paragraph 90 of plaintiffs' Complaint.

91. Ethicon denies the allegations contained in Paragraph 91 of plaintiffs' Complaint, including subparts (a.) – (c.).

92. Ethicon denies the allegations contained in Paragraph 92 of plaintiffs' Complaint.

93. Paragraph 93 of plaintiffs' Complaint states a legal conclusion as opposed to a factual allegation and requires no response by Ethicon. Ethicon denies that plaintiffs' Complaint accurately or completely states the nature of any duties allegedly owed by Defendants and Ethicon further denies that Defendants breached any duty with respect to the plaintiffs. Ethicon denies the remaining allegations contained in Paragraph 93 of plaintiffs' Complaint and all allegations inconsistent with the foregoing.

94. Ethicon denies the allegations contained in Paragraph 94 of plaintiffs' Complaint.

95. Paragraph 95 of plaintiffs' Complaint states a legal conclusion as opposed to a factual allegation and requires no response by Ethicon. Ethicon denies that plaintiffs' Complaint accurately or completely states the nature of the referenced statutes. Ethicon admits only that it supplied, manufactured, and sold Physiomesh for uses consistent with the packaging and labeling. Ethicon denies the remaining allegations contained in Paragraph 95 of plaintiffs' Complaint and all allegations inconsistent with the foregoing.

96. Ethicon denies the allegations contained in Paragraph 96 of plaintiffs' Complaint.

97. Ethicon denies the allegations contained in Paragraph 97 of plaintiffs' Complaint.

98. Ethicon denies the allegations contained in Paragraph 98 of plaintiffs' Complaint.

99. Ethicon denies the allegations contained in Paragraph 99 of plaintiffs' Complaint.

**RESPONSE TO "COUNT VI
Gross Negligence"**

100. Ethicon incorporates by reference its responses to each and every allegation contained in plaintiffs' Complaint as if fully copied and set forth at length herein.

101. Ethicon denies the allegations contained in Paragraph 101 of plaintiffs' Complaint.

102. Ethicon denies the allegations contained in Paragraph 102 of plaintiffs' Complaint.

103. Paragraph 103 of plaintiffs' Complaint makes no allegation against Ethicon and requires no response by Ethicon. To the extent a response is required, Ethicon denies that any plaintiff is entitled to any recovery or any form of relief

whatsoever from Ethicon and denies the remaining allegations contained in Paragraph 103 of plaintiffs' Complaint.

104. Ethicon denies the allegations contained in Paragraph 104 of plaintiffs' Complaint.

**RESPONSE TO "COUNT VII
Loss of Consortium"**

105. Ethicon incorporates by reference its responses to each and every allegation contained in plaintiffs' Complaint as if fully copied and set forth at length herein.

106. Ethicon denies the allegations contained in the first sentence of Paragraph 106 of plaintiffs' Complaint. The second sentence of Paragraph 106 makes no allegation against Ethicon and requires no response by Ethicon. To the extent a response is required, Ethicon denies any liability to any of the plaintiffs.

107. Ethicon denies the allegations contained in Paragraph 107 of plaintiffs' Complaint.

108. Ethicon lacks sufficient knowledge or information so as to form a belief as to the truth of the allegations contained in Paragraph 108 of plaintiffs' Complaint, and, therefore, denies those allegations. Ethicon denies any liability to any of the plaintiffs.

109. Ethicon lacks sufficient knowledge or information so as to form a belief as to the truth of the allegations contained in Paragraph 109 of plaintiffs' Complaint, and, therefore, denies those allegations. Ethicon denies any liability to any of the plaintiffs.

110. Ethicon denies the allegations contained in Paragraph 110 of plaintiffs' Complaint.

**RESPONSE TO "COUNT VIII
Punitive Damages"**

111. Ethicon incorporates by reference its responses to each and every allegation contained in plaintiffs' Complaint as if fully copied and set forth at length herein.

112. Ethicon denies the allegations contained in Paragraph 112 of plaintiffs' Complaint.

113. Ethicon denies the allegations contained in Paragraph 113 of plaintiffs' Complaint.

114. Ethicon denies the allegations contained in Paragraph 114 of plaintiffs' Complaint.

115. Ethicon denies the allegations contained in Paragraph 115 of plaintiffs' Complaint.

116. Ethicon denies the allegations contained in Paragraph 116 of plaintiffs' Complaint.

117. Ethicon denies the allegations contained in Paragraph 117 of plaintiffs' Complaint.

118. Ethicon denies the allegations contained in Paragraph 118 of plaintiffs' Complaint.

119. Ethicon denies the allegations contained in Paragraph 119 of plaintiffs' Complaint.

120. Ethicon denies the allegations contained in Paragraph 120 of plaintiffs' Complaint.

**RESPONSE TO "COUNT IX
Discovery Rule, Equitable Tolling/Estoppel"**

121. Ethicon incorporates by reference its responses to each and every allegation contained in plaintiffs' Complaint as if fully copied and set forth at length herein.

122. Paragraph 122 of plaintiffs' Complaint makes no allegation against Ethicon and requires no response by Ethicon. To the extent a response is required, Ethicon denies the allegations contained in Paragraph 122 of plaintiffs' Complaint.

123. Paragraph 123 of plaintiffs' Complaint makes no allegation against Ethicon and requires no response by Ethicon. To the extent a response is required, Ethicon denies the allegations contained in Paragraph 123 of plaintiffs' Complaint.

124. Paragraph 124 of plaintiffs' Complaint makes no allegation against Ethicon and requires no response by Ethicon. To the extent a response is required, Ethicon denies the allegations contained in Paragraph 124 of plaintiffs' Complaint.

125. Ethicon denies the allegations contained in Paragraph 125 of plaintiffs' Complaint.

RESPONSE TO "PRAYER FOR RELIEF"

In response to the unnumbered "WHEREFORE" paragraph in plaintiffs' PRAYER FOR RELIEF, Ethicon demands a jury trial and denies that any plaintiff is entitled to any recovery, including subparts (1.) – (9.), or any form of relief whatsoever from Ethicon. Ethicon respectfully requests that the Complaint be dismissed with prejudice with all costs assessed to plaintiffs and for any such other general or special relief as may be appropriate. Ethicon denies the remaining allegations contained in this paragraph.

Ethicon denies any and all allegations contained in plaintiffs' Complaint not specifically admitted hereinabove.

DEFENSES

By asserting the following defenses, Ethicon does not allege or admit that it has the burden of proof and/or the burden of persuasion with respect to any of these matters.

FIRST DEFENSE

The Court's jurisdiction over these matters derives from a Transfer Order of the United States Judicial Panel on Multidistrict Litigation. That Order did not confer jurisdiction over claims associated with any product other than Physiomesh. SecureStrap is a separate and distinct product and the allegations in plaintiffs' Complaint relating to SecureStrap are not properly before the Court.

SECOND DEFENSE

The Complaint fails, in whole or in part, to state a cause of action upon which relief can be granted.

THIRD DEFENSE

The Complaint fails to state a cause of action upon which relief can be granted due to lack of adequate product identification.

FOURTH DEFENSE

Plaintiffs' claims are barred for lack of subject matter jurisdiction.

FIFTH DEFENSE

Plaintiffs' claims are barred for lack of personal jurisdiction.

SIXTH DEFENSE

The Complaint must be dismissed because plaintiffs provided insufficient process.

SEVENTH DEFENSE

The Complaint must be dismissed because plaintiffs provided insufficient service of process.

EIGHTH DEFENSE

Plaintiffs may be barred from bringing some of the claims alleged in the Complaint because plaintiffs may lack standing and/or capacity to bring such claims.

NINTH DEFENSE

Plaintiffs may have failed to join indispensable parties or real parties in interest necessary for the just adjudication of this matter.

TENTH DEFENSE

Venue in this Court is improper.

ELEVENTH DEFENSE

Ethicon reserves and does not waive all rights under *Lexecon, Inc. v. Milberg Weiss Bershad Hynes & Lerach*, 523 U.S. 26 (1998). Ethicon specifically reserves its rights as it relates to venue and personal jurisdiction.

TWELFTH DEFENSE

This matter should be dismissed on intra-state or interstate forum non conveniens grounds.

THIRTEENTH DEFENSE

Certain of plaintiffs' claims and remedies and the defenses thereto are governed by the laws of a foreign jurisdiction or the laws of the United States.

FOURTEENTH DEFENSE

Plaintiffs' alleged causes of action have been improperly joined under the applicable Rules of Civil Procedure and the laws of the applicable state.

FIFTEENTH DEFENSE

The improper joinder of plaintiffs' alleged causes of action violates the procedural and substantive due process rights of Ethicon under the Constitutions of the United States of America and the applicable state, as well as the applicable Rules of Civil Procedure and the laws of the applicable state.

SIXTEENTH DEFENSE

The improper joinder of Defendants violates the procedural and substantive due process rights of Ethicon under the Constitutions of the United States of America and the applicable state.

SEVENTEENTH DEFENSE

Ethicon is entitled to, and claims the benefit of, all defenses and presumptions set forth in or arising from any rule of law or statute in any state whose law is deemed to apply in this case.

EIGHTEENTH DEFENSE

Ethicon specifically pleads, to the extent plaintiffs plead claims based on allegations of fraud, fraud by concealment and negligent misrepresentation claims, all affirmative defenses available to Ethicon under the rules and statutes of any state whose law is deemed to apply in this case, and under any common law principles of any state whose law is deemed to apply in this case.

NINETEENTH DEFENSE

Plaintiffs' claims are barred by the doctrine of federal preemption, as established by statute, including the preemption provision of the Medical Device Amendments, 21 U.S.C. § 360k(a), to the federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301, *et seq.*, and by state and federal case law, and are barred by the

Supremacy Clause of the United States Constitution, because the product at issue is regulated by the United States Food and Drug Administration (“FDA”) under the Medical Device Amendments, 21 U.S.C. §§ 360k, *et seq.*, to the federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301, *et seq.*, and other federal statutes and regulations.

TWENTIETH DEFENSE

At all relevant times, Ethicon was in full compliance with all applicable federal statutes and regulations, including but not limited to the Medical Device Amendments, 21 U.S.C. §§ 360k, *et seq.*, to the federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301, *et seq.*, and other federal statutes and regulations, and plaintiffs’ claims are accordingly barred.

TWENTY-FIRST DEFENSE

Plaintiffs’ claims against Ethicon are expressly and/or impliedly preempted by federal law, including but not limited to, the regulations promulgated by the FDA and contained in Chapter 21 of the Code of Federal Regulations. *See* 21 U.S.C. §§ 301 *et seq.*; *see also* Fed. Reg. 3922 (Jan. 24, 2006).

TWENTY-SECOND DEFENSE

Plaintiffs’ claims are barred because Ethicon complied with all applicable state and federal statutes regarding the product at issue including the requirements

and regulations promulgated by the FDA and contained in Chapter 21 of the Code of Federal Regulations. In the event that plaintiffs' claims are not barred, Ethicon is entitled to a presumption that the product at issue is free from any defect or defective condition as the plans or design for the product at issue or the methods and techniques of manufacturing, inspecting, and testing the product at issue were in conformity with government standards established for the industry that were in existence at the time the plans or designs for the product at issue or the methods and techniques of manufacturing, inspecting, and testing the product at issue were adopted.

TWENTY-THIRD DEFENSE

Plaintiffs' claims are barred, in whole or in part, by the deference that federal and state constitutional law and federal and state common law give to discretionary actions by the FDA under the Federal Food, Drug & Cosmetic Act, 21 U.S.C. §§ 301 *et seq.*, and regulations promulgated there under.

TWENTY-FOURTH DEFENSE

Plaintiffs' claims are barred by any applicable safe harbor doctrine to the extent federal law permits the packaging, labeling, and marketing practices alleged in the Complaint.

TWENTY-FIFTH DEFENSE

Plaintiffs' claims are governed and barred, in whole or in part, by Sections 2, 4, and 6 of The Restatement (Third) of Torts (including the comments thereto) and other applicable authorities because Ethicon complied with all applicable statutes and with the requirements and regulations of the FDA.

TWENTY-SIXTH DEFENSE

Any claims by plaintiffs relating to alleged communications with regulatory agencies in the United States government are barred in whole or in part by operation of applicable law, including the First Amendment rights of Ethicon to petition the government.

TWENTY-SEVENTH DEFENSE

Plaintiffs' claims regarding warnings and labeling are barred in whole or in part by the doctrine of primary jurisdiction, in that the FDA is charged under the law with determining the content of warnings and labeling for medical devices.

TWENTY-EIGHTH DEFENSE

Plaintiffs cannot state a claim with regard to warnings and labeling for medical devices because the remedy sought by plaintiffs is subject to the exclusive regulation of FDA.

TWENTY-NINTH DEFENSE

Plaintiffs' claim for punitive damages is barred because the product at issue was manufactured and labeled in accordance with the terms of FDA's clearance of the product at issue.

THIRTIETH DEFENSE

Plaintiffs' claims are barred in whole or in part by plaintiffs' failure to assert a safer design for the product at issue.

THIRTY-FIRST DEFENSE

Plaintiffs' claims are barred in whole or in part because the product at issue provided a benefit to users of such product and greatly outweighed any risk created by using such product, any risk could not have been avoided through the use of the highest standards of scientific and technical knowledge available at the time, the benefit provided to users could not be achieved in another manner with less risk, and adequate warnings concerning the risk were provided.

THIRTY-SECOND DEFENSE

Ethicon made no express or implied representations or warranties of any kind to plaintiffs, nor did plaintiffs rely on any representations or warranties made by Ethicon to others. To the extent plaintiffs relied upon any representations or warranties, such reliance was unjustified.

THIRTY-THIRD DEFENSE

Any express or implied warranties alleged to have been made by Ethicon were disclaimed.

THIRTY-FOURTH DEFENSE

Ethicon did not make nor did it breach any express or implied warranties and/or breach any warranties created by law. To the extent that plaintiffs rely on any theory of breach of warranty, such claims are barred by applicable law, by the lack of privity between plaintiffs and Ethicon, and/or by plaintiffs' failure to give Ethicon timely notice of the alleged breach of warranty and an opportunity to cure. Ethicon further specifically pleads as to any breach of warranty claim all affirmative defenses available to Ethicon under the Uniform Commercial Code, as enacted in any state whose law is deemed to apply in this case, and under the common law principles of any state whose law is deemed to apply in this case.

THIRTY-FIFTH DEFENSE

To the extent that any of plaintiffs' claims can be, or are construed as, alleging a violation of consumer protection laws, Ethicon specifically pleads all affirmative defenses available to Ethicon under the rules and statutes of any state whose law is deemed to apply in this case, and under the common law principles of any state whose law is deemed to apply in this case.

THIRTY-SIXTH DEFENSE

The injuries and damages allegedly suffered in this action, which are denied, were not foreseeable to Ethicon given the state of scientific knowledge and state-of-the-art at the time of the alleged injuries. At all times relevant, the product at issue conformed to state-of-the-art specifications and state-of-scientific knowledge for such product at that time, as well as all applicable statutes and regulations, including those of FDA.

THIRTY-SEVENTH DEFENSE

Plaintiffs knowingly and voluntarily assumed any and all risks associated with the use of the product at issue in this case and thus the “last clear chance” and assumption of the risk doctrines bar in whole or in part the damages that plaintiffs seek to recover herein.

THIRTY-EIGHTH DEFENSE

Plaintiffs’ claims are barred, in whole or in part, because Ethicon acted in good faith at all relevant times and gave adequate warnings of all known or reasonably knowable risks associated with the use of its product.

THIRTY-NINTH DEFENSE

At all relevant times herein, the product in question was manufactured and distributed with proper warnings, information, cautions, and instructions in

conformity with generally recognized and prevailing standards in existence at the time.

FORTIETH DEFENSE

Plaintiffs' inadequate warning claims are barred because the alleged risk of which plaintiffs claim is open, obvious, and/or a matter of common knowledge.

FORTY-FIRST DEFENSE

Plaintiffs' claims are barred in whole or in part because the product at issue was consistent with and/or exceeded consumer expectations.

FORTY-SECOND DEFENSE

Plaintiffs' claims are barred in whole or in part because the product at issue was at all times properly prepared, packaged, and distributed, and was not defective or unreasonably dangerous.

FORTY-THIRD DEFENSE

Adequate and complete warnings and instructions were provided with the product at issue. The product at issue was neither defective nor unreasonably dangerous when used according to its Instructions for Use.

FORTY-FOURTH DEFENSE

At all relevant times, the warnings and instructions accompanying the product at issue were governed by and conformed with applicable federal statutes,

rules and regulations; therefore, warnings and instructions relating to the product were presumptively adequate.

FORTY-FIFTH DEFENSE

Plaintiffs' causes of action are barred by the learned intermediary doctrine.

FORTY-SIXTH DEFENSE

Ethicon is not liable to plaintiffs because the end users of the product at issue, plaintiffs' physicians, were sophisticated users of the product.

FORTY-SEVENTH DEFENSE

Ethicon states that the sole proximate cause of the injuries and/or damages alleged by plaintiffs was the actions, omissions, or negligence of a person or persons, other than Ethicon, for whose actions, omissions, or negligence Ethicon is in no way liable. Plaintiffs are not, therefore, entitled to recover from Ethicon in this action. As to plaintiffs or to any other entity or person whose conduct or intervening negligence resulted in the alleged injuries and/or damages of plaintiffs, if any, Ethicon expressly pleads the doctrines of assumption of risk, contributory negligence, comparative fault and/or comparative negligence, as well as the provisions of any applicable comparative fault and/or comparative negligence and/or contributory negligence statute, law or policy of any applicable state.

FORTY-EIGHTH DEFENSE

The injuries and damages allegedly suffered in this action, which are denied, may have been caused, in whole or in part, by plaintiffs' own fault, which bars or proportionately reduces Ethicon's liability, if any, for plaintiffs' alleged damages.

FORTY-NINTH DEFENSE

Plaintiffs voluntarily and unreasonably chose to encounter known dangers.

FIFTIETH DEFENSE

The liability of Ethicon, if any, for plaintiffs' non-economic loss must be apportioned in accordance with the provisions of the law of any applicable state.

FIFTY-FIRST DEFENSE

In the event Ethicon is held liable to plaintiffs, which liability is expressly denied, and any other co-defendants are also held liable, Ethicon is entitled to a percentage contribution of the total liability from said co-defendants in accordance with principles of equitable indemnity and comparative contribution and pursuant to any applicable contribution or apportionment statute, law or policy of the applicable states.

FIFTY-SECOND DEFENSE

There is no causal relationship between Ethicon's conduct and the injuries and damages alleged by plaintiffs in the Complaint.

FIFTY-THIRD DEFENSE

At all times mentioned herein, plaintiffs were negligent, careless and at fault and conducted themselves so as to contribute substantially to their alleged injuries, losses, and damages. Said negligence, carelessness and fault of plaintiffs bars in whole or in part the damages which plaintiffs seek to recover herein.

FIFTY-FOURTH DEFENSE

Plaintiffs' alleged injuries, losses, or damages attributable to the use of the product at issue in this case, if any, were solely caused by and attributable to the abnormal, unforeseeable, unintended, unreasonable, and improper use or misuse which was made of said product.

FIFTY-FIFTH DEFENSE

Plaintiffs' alleged injuries, losses, or damages attributable to the use of the product at issue in this case, if any, were not legally caused by the product at issue, but instead were legally caused by intervening and superseding causes or circumstances.

FIFTY-SIXTH DEFENSE

Plaintiffs' alleged injuries, losses, or damages attributable to the product at issue in this case, if any, were caused by the acts or omissions of third parties for which Ethicon has no legal responsibility.

FIFTY-SEVENTH DEFENSE

Ethicon expressly denies any third party engaging in the acts alleged by plaintiffs was acting as Ethicon's agent or servant, at the instruction of Ethicon, or within its control. Therefore, plaintiffs' claims, to the extent they seek to recover for the acts or omissions of such third parties, are barred in whole or in part as a matter of law.

FIFTY-EIGHTH DEFENSE

Plaintiffs' causes of action are barred because the injuries and damages allegedly suffered in this action, which are denied, were due to an allergic, idiosyncratic or idiopathic reaction to the product at issue in this case, or by an unforeseeable illness, unavoidable accident, or preexisting condition, and/or another unrelated medical, genetic or environmental condition, disease or illness, without any negligence or culpable conduct by Ethicon.

FIFTY-NINTH DEFENSE

Plaintiffs' claims are or may be barred by their failure to comply with conditions precedent to their right to recover.

SIXTIETH DEFENSE

Plaintiffs' claims are barred, in whole or in part, by the doctrine of avoidable consequences.

SIXTY-FIRST DEFENSE

The claims of plaintiffs may be barred, in whole or in part, from recovery, due to spoliation of evidence and the failure to properly preserve evidence necessary to the determination of the claim.

SIXTY-SECOND DEFENSE

Plaintiffs' claims against Ethicon are barred by the doctrines of equitable estoppel, laches, consent, waiver, informed consent, release, unclean hands, res judicata, and collateral estoppel. Additionally, if any plaintiff had or has filed bankruptcy during the relevant time period of the events alleged in the Complaint or files for bankruptcy at some point in the future, the claims of any such plaintiff may be "property of the bankruptcy estate" which should be prosecuted by the bankruptcy trustee rather than plaintiff, or, if not disclosed by plaintiff on the schedules and/or statement of financial affairs, may be barred by the doctrine of judicial estoppel.

SIXTY-THIRD DEFENSE

Some or all of plaintiffs' claims may be barred by the statutes of limitations, prescription, and/or statutes of repose of any applicable state.

SIXTY-FOURTH DEFENSE

To the extent plaintiffs' claims are based on alleged misrepresentations or omissions made to the FDA, such claims are barred by *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001).

SIXTY-FIFTH DEFENSE

Plaintiffs' alleged damages, if any, are barred in whole or in part by plaintiffs' failure to mitigate such damages.

SIXTY-SIXTH DEFENSE

The sale, labeling and marketing of the product at issue in this litigation is not, and was not, likely to mislead or deceive the public.

SIXTY-SEVENTH DEFENSE

The product at issue was altered after the product left the control, custody and possession of Ethicon, and said alteration relieves Ethicon of any and all liability.

SIXTY-EIGHTH DEFENSE

Any strict liability cause of action for relief is subject to the limitations set forth in Restatement (Second) of Torts, Section 402A, comment k.

SIXTY-NINTH DEFENSE

Plaintiffs' claims are barred in whole or in part under Section 402A, comment j and k of the Restatement (Second) of Torts.

SEVENTIETH DEFENSE

Plaintiffs' claims are barred, in whole or in part, to the extent plaintiffs have released, settled, entered into an accord and satisfaction or otherwise compromised their claims by any means.

SEVENTY-FIRST DEFENSE

Any recovery by plaintiffs must be reduced or offset by all amounts paid, payable by, or available from collateral sources.

SEVENTY-SECOND DEFENSE

Plaintiffs' Complaint fails to state a claim upon which relief can be granted as to costs, attorney's fees, expert fees, expenses, pre-judgment interest, post-judgment interest, refund, rescission, unjust enrichment, disgorgement or restitution.

SEVENTY-THIRD DEFENSE

The Complaint fails to state facts sufficient to entitle plaintiffs to an award of punitive damages.

SEVENTY-FOURTH DEFENSE

No act or omission of Ethicon was malicious, oppressive, willful, wanton, reckless, or grossly negligent, and therefore any award of punitive damages is barred.

SEVENTY-FIFTH DEFENSE

Plaintiffs' claims for pain and suffering are barred because they violate Ethicon's rights to procedural and substantive due process and equal protection as guaranteed by the Constitutions of the United States and any state whose law is deemed to apply in this case.

SEVENTY-SIXTH DEFENSE

The imposition of punitive or exemplary damages would violate Ethicon's constitutional rights, including but not limited to those under the due process clauses in the Fifth and Fourteenth Amendments to the Constitution of the United States, and the equivalent or correlative applicable provisions in the Constitutions, common law, public policy, applicable statutes and court rules of the applicable states to these amendments and the excessive fines clause in the Eighth Amendment to the Constitution of the United States and the double jeopardy clause in the Fifth Amendment to the Constitution of the United States. They would further violate Ethicon's rights to the extent that punitive damages awarded

to any plaintiff are (1) imposed by a jury that is not provided standards of sufficient clarity for determining the appropriateness, and the appropriate size, of such a punitive damages award; is not adequately and clearly instructed on the limits on punitive damages imposed by the principles of deterrence and punishment; is not expressly prohibited from awarding punitive damages, or determining the amount of an award thereof, in whole or in part, on the basis of invidious discriminatory characteristics, including the corporate status, wealth, or state of residence of defendant; or is permitted to award punitive damages under a standard for determining liability for such damages which is vague and arbitrary and does not define with sufficient clarity the conduct or mental state which makes punitive damages permissible; (2) not subject to independent de novo review by the trial and appellate courts for reasonableness and the furtherance of legitimate purposes on the basis of objective legal standards and in conformity with the United States Constitution as amended or any applicable State constitution as amended; (3) imposed where state law is impermissibly vague, imprecise, or inconsistent; (4) subject to no predetermined limit, such as a maximum multiple of compensatory damages or a maximum amount; (5) imposed on the basis of anything other than Ethicon's conduct within the State where each plaintiff resides, or (6) imposed in

any other way subjecting Ethicon to impermissible multiple punishments for the same alleged wrong.

SEVENTY-SEVENTH DEFENSE

Ethicon specifically incorporates by reference all standards of limitations regarding the determination and enforceability of punitive damage awards as applied to the state and federal courts of the applicable states under the Due Process Clause of the Fourteenth Amendment to the United States Constitution.

SEVENTY-EIGHTH DEFENSE

With respect to plaintiffs' demand for punitive damages, Ethicon specifically incorporates by reference all standards of limitations regarding the determination and enforceability of punitive damage awards that arise under *BMW of North America, Inc. v. Gore*, 517 U.S. 559 (1996); *Cooper Industries, Inc. v. Leatherman Tool Group, Inc.*, 532 U.S. 424 (2001); *State Farm Mut. Auto Ins. Co. v. Campbell*, 538 U.S. 408 (2003); *Philip Morris USA v. Williams*, 549 U.S. 346 (2007), and their progeny, as applied by the federal courts of appeals, together with all such standards applicable under any other state's law.

SEVENTY-NINTH DEFENSE

Ethicon asserts the provisions of all applicable statutory caps on damages of any sort, including punitive, non-economic or exemplary damages, under the laws of any applicable state.

EIGHTIETH DEFENSE

Ethicon specifically pleads as to plaintiffs' claims for punitive damages, all affirmative defenses available to Ethicon under the rules and statutes of any state whose law is deemed to apply in this case, and under any common law principles of any state whose law is deemed to apply in this case.

EIGHTY-FIRST DEFENSE

Ethicon specifically pleads as to plaintiffs' strict liability claims, all affirmative defenses available to Ethicon under the rules and statutes of any state whose law is deemed to apply in this case, and under any common law principles of any state whose law is deemed to apply in this case.

EIGHTY-SECOND DEFENSE

Ethicon specifically pleads as to plaintiffs' negligence claims all affirmative defenses available to Ethicon under the rules and statutes of any state whose law is deemed to apply in this case, and under any common law principles of any state whose law is deemed to apply in this case.

EIGHTY-THIRD DEFENSE

Ethicon hereby gives notice that it intends to rely upon and incorporate by reference any affirmative defenses that may be asserted by any co-defendant in this lawsuit.

EIGHTY-FOURTH DEFENSE

The injuries complained of were not proximately caused by any product manufactured, sold or distributed by Ethicon, nor were the injuries caused by any acts or omissions on the part of Ethicon.

EIGHTY-FIFTH DEFENSE

To the extent that plaintiffs' claims are based on a theory providing for liability without proof of causation, the claims violate Ethicon's rights under the United States Constitution.

EIGHTY-SIXTH DEFENSE

Ethicon is entitled to credit for any settlement of claims for alleged injuries and damages made by plaintiffs with any other defendant(s) or other person or entity subsequently joined to this action.

EIGHTY-SEVENTH DEFENSE

Plaintiffs' Complaint fails to state a claim for a manufacturing defect because such allegations fail to state a plausible claim for relief under the standards

articulated in *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009), and *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). Accordingly, plaintiffs' manufacturing defect claim should be dismissed.

EIGHTY-EIGHTH DEFENSE

As it relates to any causes of action asserted in a plaintiff's Short Form Complaint that are not included in the Complaint, Ethicon denies liability and relies on all defenses available under the law and equity.

EIGHTY-NINTH DEFENSE

Any causes of action that are alleged in a complaint that are not alleged in a subsequent Short Form Complaint are abandoned.

NINETIETH DEFENSE

Ethicon reserves the right to assert any additional defenses and matters in avoidance, which may be disclosed during the course of additional investigation and discovery.

DEMAND FOR JURY TRIAL

Ethicon specifically requests and demands a trial by jury of 12 persons as to issues so triable.

WHEREFORE, Defendant Ethicon, Inc. prays that:

- (1) Plaintiffs take nothing by reason of their Complaint;

- (2) The Complaint be dismissed in its entirety and that a Judgment against plaintiffs and in favor of Ethicon, Inc. be entered;
- (3) Ethicon, Inc. be awarded its costs and expenses; and
- (4) This Court award Ethicon, Inc. any other and general or specific relief as this Court may deem just and proper.

Respectfully submitted,

/s/ William M. Gage

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FONT CERTIFICATION

Pursuant to Local Rule 7.1 D, I hereby certify that the foregoing document was prepared using Times New Roman 14 point type as provided in Local Rule 5.1.

/s/ William M. Gage
William M. Gage